

- E, Ea, which may be provided on one or both sides of the blade, can have interdigitated elements C1, C2 (Figs. 1 to 4), or may comprise alternate layers of conductive and insulating material (Figs. 5 to 7). Blade 10 may be of insulating material (e.g. glass or ceramic), or of conductive material in which case it can be used as a common electrode interacting with electrodes E, Ea. The instrument may be powered with D.C. or, preferably, constant-voltage, high frequency A.C., the voltage being kept low enough to prevent arcing.



$s/s.$

FIG 4

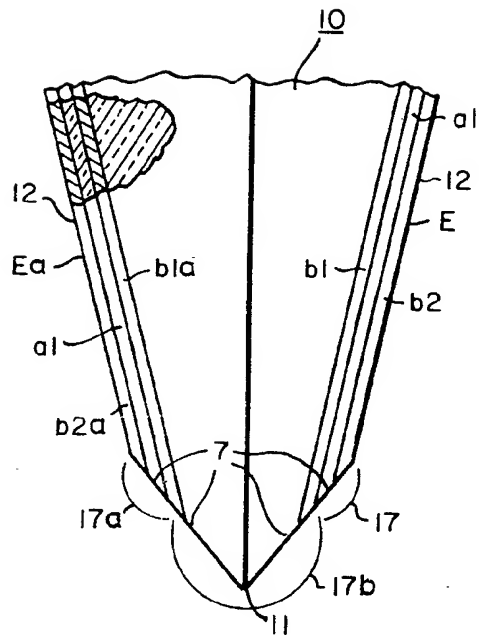


FIG. 5

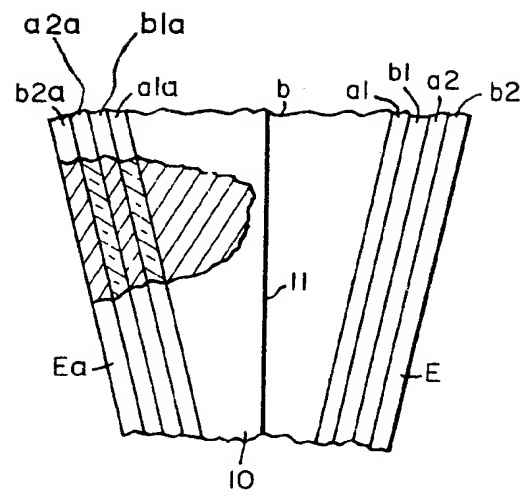


FIG. 6

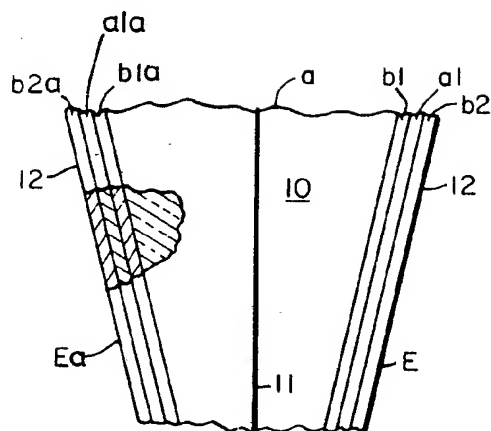


FIG. 7

SPECIFICATION

Surgical cutting instrument

5 This invention relates to surgical cutting instruments.
 During application of a surgical knife or scalpel bleeding can be reduced by cauterizing the cut tissue through heat. It is known that this can be obtained,
 10 for example, by applying resistance elements near the cutting edge of a scalpel which is electrically heated to provide a temperature of 200-500°C. in contact with the tissue. In doing so, however, parts of the blade not in contact with tissue may become
 15 grossly overheated, presenting a hazard to both patient and surgeon. Several methods have been recommended to overcome this problem. Generally, all have disadvantages. For example, segmented heating elements require individual temperature-
 20 power control systems; heating elements with a large negative temperature coefficient of resistance (TCR) require a very high voltage drive; and, high frequency electric discharge applied through the body of the patient produces bad scars and is hard to
 25 control.

An object of the present invention is to provide a surgical cutting instrument having a blade portion and cutting edge therefor which is adapted with electric input elements for cutting the tissue and cauterizing
 30 the surfaces of the incision, thereby allowing surgery to be more rapidly performed. This is accomplished in accordance with the illustrated embodiments of this invention by applying electrodes of opposed polarity to the blade near the cutting
 35 edge. With an electrical potential applied, no current will flow between the electrodes and no heat is produced unless the electrode gap is bridged by a conducting medium, such as moist tissue rendered conductive by the presence of physiological fluid.
 40 Heat is then generated by electric discharge below an arcing threshold in all areas where the blade is in contact with moist tissue. No electric discharge or heat occurs elsewhere. Moreover, if movement of the blade is halted, heat generation will automatically diminish as the tissue becomes dry as a result
 45 of cauterization. Cauterization and hemostasis may occur in both intact and incised tissue.

The electrodes may be made of films of platinum, palladium and other stable metals or alloys satisfying
 50 physiological requirements. While the potential applied may be DC or AC, the latter is preferred. In AC mode of operation, particularly at higher frequencies, the system will react as a lossy capacitor when a high conductivity material such as salt-
 55 containing water appears within the electrode gap or fringing field between electrode segments. In this case, the heating effect can be controlled by frequency modulation.

The substrate or blade is formed of an insulating
 60 material, preferably a glass or glass-ceramic or ceramic with fine grains. The present invention may take various forms for example:

(a) a substrate either conductive or non-conductive having interleaved alternate layers of
 65 conductors and insulators near the cutting edge to

produce heating by conduction or discharge through the moist incised tissue;
 (b) sets of longitudinal electrodes applied to one or both sides of blade having interleaved conductive
 70 fingers;
 (c) a metallic cutting edge providing a common connection to one electrode on both sides of the blade; or
 (d) one electrode connected on each side of blade,
 75 interleaving across the cutting edge.

The handle of the cutting instrument is electrically insulated from the blade. To permit comfortable use of the instrument, the handle and blade are light-weight detachable modules for easy replacement
 80 and interchangeability with blades having cutting edges of various shapes and sizes determined by the nature of the incision to be made and the tissue to be cut.

In the accompanying drawings:
 85 FIG. 1a is a schematic side view of an embodiment of the present invention,
 FIG. 1b is a schematic and sectional view taken along line 1b-1b of Fig. 1a illustrating the basic principle of operation of the present invention,
 90 FIGS. 2-3 show variations of the present invention wherein an elongated electrode is located on one or both sides of a blade with inter-leaved patterns of conductive fingers,
 FIG. 4 is a fragmented end section taken along line
 95 4-4 of FIG. 3,
 FIG. 5 is a partially fragmented end view of the blade illustrated in Fig. 2,
 FIGS. 6 and 7 are fragmented end section views of variations on the embodiment of the present invention
 100 illustrated in FIG. 2, showing respectively a metallic cutting edge with interleaved layered electrodes and insulators, and a monolith blade structure.

Fig. 1 illustrates in schematic form a preferred
 105 embodiment of the present invention. A substrate of insulating material forms a surgical instrument or blade 10 having a cutting edge portion 11. The blade 10 carries electric input elements 12 which are conductive and are labelled respectively as electrodes E and Ea. The input elements 12 may be metal foil overlays or coatings having interdigitated discrete
 110 elements c1 and c2 for respective electrodes E and Ea. Conductors 13 are electrically coupled to input elements 12 via leads or contacts 18 and are supplied with high frequency electrical energy.

The present invention will be further described below mainly with respect to incised tissue but it should be understood that incision is not absolutely
 115 necessary for the invention to provide hemostasis.

The normally moist tissue of a human may be cauterized by the application of electrical energy in accordance with the principles of the present invention since the moist fluid associated with tissue conducts. Thus successful experiments using various
 120 forms of animal tissue have shown that the desired effect of cauterization can occur merely by placing the instrument 10 in contact with moist tissue. As physiological fluid dries the process diminishes to a low level but may continue if the instrument is left in
 125 one position. The principle described herein does

not therefore require incision, release of fluid and cauterization to produce hemostasis as a multistep process but in reality requires the passage of electrical energy through any available electrolytic medium in or on the tissue surfaces to be cauterized. For purposes of explanation however, the main thrust of the disclosure will refer to the practice of incising and cauterizing tissue simultaneously.

In Figure 1b tissue 14 is incised at 15 by the cutting edge 11 and opposed surfaces 15a-15b of incision 15 has a surface layer of conductive physiological or body fluid 16 exposed. The spacing of blade 10 and surfaces 15a-15b is exaggerated for clarity but in reality they are in intimate contact. The electrical power is conducted to cutting edge 11 via the electric input elements 12 and, physiological fluid 16 provides one or more paths 17 for contact conduction from one electrode E to the other Ea. A similar process may occur if input elements 12 are also provided for the left side of blade 10. Input elements 12 located on both sides of blade 10 are preferred.

AC is preferred since undesirable polarization of the electrodes E-Ea and muscular stimulation is possible when DC is used. Further, high frequency AC of 100 kHz—10 mHz is preferred since the input voltage can be as low as 30-50 volts, well below a threshold for arcing.

As the incision 15 is cauterized by the heat generated along conduction paths 17, the body fluid 16 is dried by the heating action. Thus conduction paths 17 disappear and the process is self-limited. As the incision 15 is lengthened or deepened the newly incised portions again release body fluid 16 and the current flows in that newly moistened area. The present invention does not require complex control of portions or segments of the blade 11 since the current paths 17 are produced only when the tissue 14 in incision 15 is moist, i.e. there is body fluid 16 present, resulting from a fresh incision. Wide temperature excursions causing overheating of tissue or portions of the blade 10 is thereby eliminated.

Referring now to Figs. 2 and 3 of the drawing, there is shown another preferred embodiment of the present invention, wherein similar elements illustrated and explained with regard to Fig. 1 are referenced with the same numerals. The surgical cutting instrument 10 includes the blade cutting edge 11 formed in the desired shape of a surgical cutting instrument which is detachable from handle or holder not shown. The blade 10 may sometimes hereinafter be referred to as a substrate as it carries the electrical input elements 12 thereon disposed in the region of the cutting edge 11. Electrical connections 13 couple input elements 12 to a high frequency voltage source 8 via contacts 18-18a, cable 19 and cable connectors 20-20a. The input elements 12 may be comprised of electrodes E and Ea, the former deposited as a layer of conductive film along the cutting edge 11 and having interdigitated fingers c1. The arrangement is similar to Figure 1 except that the electrode E1 is adjacent and deposited on the cutting edge. The electrode Ea is spaced away from cutting edge 11 and carries fingers c2 which are interdigitated with the fingers c1 of electrode E to provide potential current path sites 17 from elec-

trode E to Ea.

As mentioned previously, it is contemplated, in the present invention that the tissue 14 is conductive fluid due to the presence of body fluid 16 bound up in cells (not shown) on the surfaces of intact tissue or surfaces of newly incised tissue, (see Fig. 1). Such fluid satisfactorily conducts electricity. Once the region of the incision 15 is cauterized, the fluid 16 in the vicinity of the incision 15 or area of contact with blade 10 dries and the electrical current reduces by a self-limiting process. This localizes the portion of the input element 12 in which power is dissipated to the portion in contact with moist tissue 14 (see Fig. 1b). The tissue temperature near such portions of the input element 12 may thus be maintained substantially constant.

In the embodiments of the present invention, illustrated in Figs. 1a-2, heating elements 12 are disposed near the cutting edge 11 on one side of blade 10. The input element 12 is formed with the interdigitated comb-like fingers c1 and c2 projecting from respective electrodes E and Ea towards the opposite one. This interdigitation provides paths 7 for current flow across spaces 23 on the surface of the substrate 10. In Fig. 1a the input element 12 is spaced away from the cutting edge 11 while in Fig. 2 one electrode E of input element 12 is formed as a part of the cutting edge 11 and may be coextensive therewith.

In Figs. 3 and 4 the electrode Ea with its comblike fingers c2 is deposited on one side (right) of substrate 10 and the fingers c2 extend across cutting edge 11 to the opposite side. Likewise the electrode E is deposited on the opposite side (left) of the blade with portions of its fingers c1 extending across the cutting edge 11 to the side shown. The fingers c1 and c2 form an interdigitated pattern with each other. Current paths 7 are provided laterally along the cutting edge 11 across insulated spaces 23 while the blade 10 is in contact with moist tissue 14 (see Fig. 1b). The current paths 7 of input element 12 are all parallel-connected between the electrodes E and Ea.

Contacts 18-18a, leads 13, and cable connectors 20-20a may be formed of a material such as platinum, gold, tungsten or the like, which makes good contact with the input element 12 material and does not readily oxidize at elevated operating temperatures. The input element 12 may consist of tin oxide or possibly one of the noble metals mentioned above.

Referring now to Figure 6 of the drawing, there is shown another preferred embodiment of the present invention, wherein similar elements illustrated and explained with regard to Fig. 1 are referenced with the same numerals. The surgical cutting instrument 10 includes the blade cutting edge 11 formed in the desired shape of a surgical cutting instrument which is detachable from handle or holder 9. The blade 10 may sometimes hereinafter be referred to as a substrate as it carries the electrical input elements 12 thereon disposed in the region of the cutting edge 11. Electrical connections 13 couple input elements 12 to a high frequency voltage source 8 via contacts 18-18a, cable 19 and cable connectors 20-20a. The input elements 12 may be comprised of electrodes E and Ea formed in layers of continuous conductive

films or foils b1 and b2 being interleaved or layered with an insulating material or film al. . . ., each successively deposited on substrate 11. Layering of conductive films b1, b2, etc., and insulation a1 . . .

- 5 may use conventional vapour-deposition processes, metal foil and film lamination techniques or other concepts hereinafter described. The conductive films b1, b2-b1a, b2a used for the input elements 12-12a may be tin oxide or other similar material. Electrical energy from high frequency voltage source 8 is delivered on both sides of blade 10 to respective conductive films b1 and b2, b1a and b2a. The high frequency signal cannot bridge the insulated spaces 7 between the conductive films b1 and b2 unless there is a conductive medium (e.g. body fluid 16) bridging the gap. Thus if the cutting edge 11 of blade 10 were in a conductive fluid, current would flow between conductive films b1 and b2 and b1a and b2a. Fig. 6 illustrates conductive paths 17 and 17a and 17b. Conduction can occur between films on one side or across the cutting edge 11 depending on the relative polarity of films b1, b2 and b1a, b2a.

As mentioned previously, it is contemplated, in the present invention that the tissue 14 is conductive due to the presence of body fluid 16 bound up in cells (not shown), on the surfaces of intact tissue or surfaces of newly incised tissue. Such fluid satisfactorily conducts electricity. Once the region of the incision 15 is cauterized, the fluid 16 in the vicinity of the incision or area of contact with blade 10 dries and the electrical current reduces by a self-limiting process. This localizes the portion of the input element 12 in which power is dissipated to the portion in contact with moist tissue 14. The tissue temperature near such portions of the input element 12 may thus be maintained at a sufficiently high temperature to effect cauterization and hemostasis.

Figs. 7 and 8 are variations of the present invention shown in partially fragmented end section. In Fig. 7 the blade or substrate 10 is formed of conductive material b. Insulating layers a1, a1a and a2, a2a are interleaved with conductive films b1, b1a and b2, b2a to form electrodes E and Ea. The blade 10 may be used as a common, electrically interacting with the conductive films b1, b1a, b2, b2a, etc.

In Fig. 8 the blade 10 may be a ceramic monolith of insulating material a having respective interleaved layers of co-fired or successively fired conductive and insulating films a1... b1... and primed counterparts on opposite sides of the cutting edge 11.

The substrate 10 has a small and well controlled inter electrode spacing imposed very close to the cutting edge 11 by laminating the thin layers (10 μ to 100 μ) of the alternate layers of respective dielectric and conductive films or foils a1... and b1... In this arrangement wear of the blade cutting edges 11 will not drastically effect the spacing of the conductor configuration.

Typical materials usable as a dielectric are polymeric membranes, lacquer films, glazing, mica sheets, etc. Metals for electrodes can be chosen from precious and semiprecious metals mentioned above, as well as stainless steels and others, depending on the intended use. In the case of the monolithic structure of Fig. 8, it is possible to cofire

screened-on dielectrics a1... and conductive films b1... as well as cable connectors 20-20a, leads 13 and contacts 18-18a. This approach allows a better control of the planarity of the cutting edge 11 and heating surfaces of the blade 10.

The spacing of the electrodes E-Ea with respect to the cutting edge 11 should be accomplished by a narrow interelectrode spacing d , i.e. the distance d equals the path length from one electrode to the other across cutting edge 11. For input element 12, running parallel to the cutting edge 11, the spacing d is twice the distance $\frac{d}{2}$ from the cutting edge 11 to each of the electrodes E and Ea.

Electrodes E-Ea may have a spacing d of 1.5 millimetres ($\frac{d}{2}$ 0.75 millimeters) and be powered with

high frequency (100 kilohertz) power of 100 volts or less, without arcing. Low voltage is preferred generally from about 20 to 80 V.

In each of these embodiments, the cable connectors 20-20a are coupled to a suitable high frequency voltage generator 8 (see Fig. 2), which may be a conventional, well-regulated power supply which is capable of delivering the total current required by all portions of input element 12 while maintaining the voltage between electrodes E-Ea substantially constant as various portions conduct. With constant voltage applied to the electrodes, the moist regions draw correspondingly more current and dissipate more power than the dry regions, thereby tending to maintain the tissue in contact with input element 12 all along the cutting edge 11 at a sufficiently high temperature to effect cauterization and hemostasis. The operating temperature at the cutting edge 11 may be controlled by altering the output power and frequency of the high frequency voltage generator 8. Likewise auxiliary heat for the heater may be supplied by a well regulated DC source.

Experimental conventional HF generators and power supplies have been used to test the principles of operation of the present invention. To assure substantially uniform operating temperature over the length of the cutting edge 11, the input element 12 should have substantially uniform resistance per unit area, lower than the resistance of the tissue exposed to the input element 12.

Metals for electrodes can be chosen from precious and semiprecious metals mentioned above, as well as stainless steels and others, depending on the intended use.

An important advantage of the use of closely spaced electrodes E-Ea is that the low voltage essentially eliminates arcing typical for most high frequency electrosurgical devices presently known. At low voltages, without arcing, flow of electricity between opposite electrodes is possible only by contact with moist tissue 14 contacting high conductivity physiological fluids 16. With cauterizing, the incised tissue 15 surfaces become dry and the conductive connection between electrodes E-Ea ceases because the voltage is not sufficient for arc formation. This feature has the advantages of avoiding tissue burns, self-limiting control of electric power, and constant voltage and power consumption control with respect

to cutting rate or variation thereof in the area of the tissue to be incised at any instant in time.

In the preferred embodiment of Fig. 1 each blade 10 shown has a similar end section profile. For purposes of explanation, the arrangement of Fig. 1 will be detailed bearing in mind the other similar arrangements. The substrate or blade 10 may be manufactured from a hard glass, glass-ceramic or ceramic sufficiently fine grained or homogeneous and strong for making a good cutting edge. The thickness of the blade 10 decreases to about 0.15 millimetres near the cutting edge 11. Two strips of appropriately shaped metal foil, or metal coatings *ba* are applied to one or both sides of the blade 10 before the cutting edge 11 is formed. In this manner one assures that the electrodes E-Ea are placed as close as possible to the cutting edge 11 which is formed by removal of some of the material of the heating element 12. For example the glass known as Corning Code 1723 glass can be sealed to molybdenum foil by pressing in a vacuum at elevated temperature above the softening point of the glass. Other glasses and ceramics can be used with matched thermal expansion by sealing foils or by other metallizing processes. For very thin metal films (less than 1 millimetre) or films made from ductile metal such as aluminum, silver, platinum, gold, etc., matching thermal expansion is less critical.

For the blade 10 illustrated in Fig. 1 strips of 0.1 millimetre molybdenum metal cover the tapered portion 26 of the substrate 10 near the cutting edge 11. Such a coating of foil also provides for some reinforcement of the substrate 11 in the tapered portion 26. If thin electrically conductive films are used for the input element 12, the glass in the tapered region 26 could be formed thicker for providing more strength. Thin metal films of less than one millimetre are preferably made of tin oxide, platinum or gold or alloys thereof because of their good adherence to the substrate 10 and their electrochemical stability.

It has been mentioned that the operation is self-controlling if the voltage is kept at a certain value below the threshold for arcing. For the device shown in Fig. 1 the voltage may be in the range of about 50 to 20 volts as determined by the spacing between the electrodes E-Ea near the cutting edge 11. Any decrease in the spacing of the electrodes E-Ea will decrease the required voltage. Power dissipation will vary the cutting rate and the contact area with the incised tissue at 15, and it is contemplated that the range of power dissipation is between about 5 and about 50 watts. High frequency power is used to minimize nerve stimulation and to avoid electrical polarization of the incision 15 including side reactions. The range of frequencies which has been found useful is between about 10 kilohertz and 10 megahertz. With such a wide frequency range a power supply having a variable frequency output can be used as a means of impedance matching the circuit of the power supply with the circuit of the surgical instrument 10 including the input element 12, and the electrical connections coupling power thereto. Generally the power supply setting should be chosen so as to maximize power at the lowest

possible voltage for a given blade configuration.

The present invention is useful for other applications requiring a heated cutting edge, notwithstanding the main thrust of the disclosure for a surgical instrument. For example the invention could be used to cut materials which are electrically conductive or rendered conductive by the presence of working fluids and the like, so that cutting and perhaps sealing could simultaneously occur.

CLAIMS

1. A surgical instrument adapted to be coupled to a source of electrical power for cauterizing tissue which is moist and electrically conductive due to the presence of physiological fluid and for simultaneous hemostasis thereof, the instrument comprising: a source of electrical power; a substrate support means having as a portion thereof a cutting edge region for incising tissue and an electrically-conductive input element adapted to be electrically coupled to the source of power, said input element disposed in the vicinity of said cutting edge region, defining a cutting edge to contact tissue including at least two electrically isolated conductors to conduct electrical power along a plurality of parallel electrical current paths from one conductor to the other for directly heating the tissue at the cutting edge region in response to the electrical power applied to said electrically conductive material, the tissue being moist due to the presence of body fluid and electrically completing said parallel current paths from one conductor to the other; and connection means on said instrument providing electrical connections to said input element for supplying the electrical power thereto.

2. A surgical instrument as claimed in claim 1, wherein said conductors comprise: a pair of electrodes including discrete interdigitated elements which are disposed on the substrate support means in substantially parallel spaced relationship with each other adjacent the cutting edge and transversely therewith, wherein the plurality of parallel current paths are oriented substantially laterally along the cutting edge.

3. A surgical instrument as claimed in claim 1, wherein said conductors comprise: a pair of electrodes disposed on opposite sides of said substrate; including a plurality of discrete elements disposed to traverse the cutting edge and disposed such that free ends thereof are spaced apart from electrodes on opposite sides of said substrate.

4. A surgical instrument as claimed in claim 1 wherein said conductors comprise electrodes disposed on opposite sides of the substrate, the parallel current paths traverse the cutting edge region.

5. A surgical instrument as claimed in claim 1 wherein said conductors comprise electrodes disposed such that at least one lies along said cutting edge region.

6. A surgical instrument as claimed in any of claims 2-5 wherein the source of alternating current power coupled to the electrodes is operative to produce an output having a selected amplitude and frequency, such that, current paths may be completed from one electrode to the other below an arcing threshold for the selected amplitude and frequency

of the source and the space relationship of the electrodes.

7. A surgical instrument as claimed in claim 6 wherein said electrodes are closely spaced such that for a given amplitude, current will flow only when the input element is in contact with a relatively highly conductive medium.

8. A surgical instrument as claimed in claim 7 wherein said electrode spacing is between about 1 and 0.1 millimetres and the electrical power ranges between 5 and 50 watts such that an electrical potential across said electrodes is between about 20 and 80 volts, which potential is below a threshold for electrical arcing.

9. A surgical instrument as claimed in claim 1 wherein said input element is further defined as comprising a plurality of discrete elements.

10. A surgical instrument as claimed in claim 1 wherein said input elements are formed in alternate layers of dielectric and conductive materials.

11. A method of affecting simultaneous cauterization and resulting hemostasis in tissue comprising the steps of: contacting the tissue with a tissue cauterizing means; establishing an elevated temperature in tissue by conducting current only along a plurality of selected substantially parallel current paths located along said cauterizing means which are in contact with relatively moist tissue; dissipating power in regions of the cutting edge which are selectively conductive upon contact with moist tissue for the purpose of cauterizing said tissue and thereby producing hemostasis.

12. A method according to claim 11 comprising: conducting current to opposed electrodes along a plurality of substantially parallel current paths along the cauterization means; completing said substantially parallel current paths by contacting such moist tissue and thereby dissipating power in regions of said cauterization means responsive to selective conduction of said regions.

13. A method according to claim 11 wherein: conducting of current along the plurality of substantially parallel current paths is dependent on the conductivity of the tissue.

14. A method according to claim 11 wherein dissipating power in the region of the cauterization means in contact with moist tissue results in increasing the resistance of the parallel current paths by decreasing moisture of the tissue.

15. A method according to claim 12 wherein: establishing an elevated temperature near the cauterization means along the parallel current paths includes the step of impressing a voltage of from about 20 volts to about 80 volts upon the plurality of parallel current paths.

16. A method according to claim 15 wherein, impressing the voltage includes the step of alternating said voltage conducted to the opposed electrodes at a frequency of from about 10 kHz to about 10 mHz.

17. A method according to claim 12 further including the step of: maintaining the power to said parallel current paths at below a selected arcing threshold level thereby suppressing arcing from the electrodes.

18. A method according to claim 17 further including the step of: maintaining the electrodes in a selected spaced relation below the selected arcing threshold for a level of current conducted thereto.

19. A method according to claim 12 further including the step of: orienting the current paths in at least one of the directions along and across the cauterization means.

20. A cutting instrument adapted to be coupled to a source of electrical power for cutting material which is electrically conductive comprising: a source of electrical power; a substrate support means having as a portion thereof a cutting edge region and an electrically-conductive input element adapter to be electrically coupled to the source of power; said input element disposed in the vicinity of the cutting edge region to contact the material to be cut including at least two electrically isolated conductors to conduct electrical power along a plurality of parallel electrical current paths from one conductor to the other for directly heating the material at the cutting edge in response to the electrical power applied to said electrically conductive material; the material being electrically conductive completing said parallel current paths from one conductor to the other; and connection means on said instrument providing electrical connection to the input element for supplying electrical power thereto.

21. A surgical cutting instrument substantially as described with reference to the accompanying drawings.

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